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Effects of corneoscleral topography on soft contact lens performance: A pilot study

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ABSTRACT

To quantify corneoscleral junction (CSJ) topography in soft contact lens (SCL) wearers, and assess the association between the CSJ and SCL performance and subjective comfort, forty-four adapted SCL wearers (16 Asians, 16 Caucasians, 12 Latinos) were recruited for the present study. Corneal topography was taken with a Medmont E300 (Medmont International, Pty Ltd.). CSJ images were taken with a commercial OCT (Bioptigen, Inc.). Our published CSJ image analysis technique was used to describe the geometric properties of the CSJ using the sum of squared orthogonalized residuals (SSRo). Multivariable mixed effects models were employed to examine associations between SSRo and subject demographics, ocular characteristics, SCL fit and performance, and comfort. The SSRo was significantly related to quadrant ($p < 0.001$), ethnicity ($p = 0.014$), and horizontal corneal shape factor ($p = 0.044$). The nasal quadrant had the largest SSRo, indicating the steepest CSJ profile and/or the most irregular CSJ surface, followed by the inferior quadrant. The superior and temporal quadrants had the smallest SSRo, indicating relatively flat and even CSJ topography. Caucasians had the steepest and/or most irregular CSJ compared with Latinos and Asians. Less inferior-superior heterogeneity in the SSRo was associated with greater comfort after 6 h of lens wear. The SSRo was proved to be a useful tool to quantify CSJ geometry in SCL wearers. Significant differences in the SSRo were found among quadrants and ethnic groups. Better subjective comfort after 6 h of SCL wear was associated with a smaller difference in the SSRo between the superior and inferior quadrants.

1. Introduction

Contact lens performance and ocular surface anatomy are interrelated, and the relationships between them may collectively influence subjective comfort during lens wear [1]. The importance of central and mid-peripheral corneal topography in determining the fitting parameters of a rigid or soft contact lens (SCL) has been investigated extensively [2,3]. However, the influence of the corneoscleral junction (CSJ) – the approximately 1.5 mm wide transition zone between cornea and sclera – on contact lens fit and subjective comfort has not been thoroughly investigated [4]. The CSJ has been relatively neglected in the research area of anterior ocular anatomy and contact lens fit partially due to the fact that conventional corneal topographers do not cover a large enough region to include the CSJ. In particular, there has been a lack of quantitative metrics to describe the geometric characteristics of the CSJ.

In recent years, imaging of the CSJ has become achievable with optical coherence tomography (OCT), but quantification of CSJ topography has remained challenging. Among the few available studies of CSJ topography, angle measurement has been used conventionally for quantification [4,5]. However, because of the geometric properties of the CSJ — the transition between two curves with different radii of curvature (~8 mm for the central cornea [6] and > 12 mm for the sclera [7]) – there is an inherent uncertainty in the quantification of the CSJ profile by angle measurement. To more accurately quantify CSJ topography, we previously described a novel metric – the sum of the squared orthogonalized residuals (SSRo) – based on semi-automated image analysis of OCT images of the CSJ [8]. The SSRo is calculated from the deviations of data points along a CSJ profile from a linear regression, and is invariant to the orientation of the CSJ profile relative to the image frame. We assessed the repeatability and reproducibility of this metric in neophyte subjects, and confirmed its capability to quantify the CSJ profile. In this study, we employed this validated OCT-based method to quantify the CSJ of SCL wearers and to investigate how lens performance and subjective comfort are affected by CSJ topography alone while maintaining minimal variation in other factors

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known to be related to lens-wearing comfort.

2. Methods

2.1. Subjects

Adapted SCL wearers were recruited from the University of California, Berkeley campus and adjacent community. Subjects were between the ages of 18 and 39 years. All subjects were experienced spherical SCL wearers who reported having had a comprehensive eye exam within the previous 2 years, who reported wearing contact lenses at least 5 days per week for at least 1 year, and who did not wear rigid lenses or wear their lenses on an overnight basis. Subjects were screened to ensure they were free from any conditions (e.g., allergies, GPC, dry eye), injuries, behaviors or use of any ophthalmic drug that might adversely affect ocular health or otherwise limit the ability to wear contact lenses on a full-time basis. Informed consent was obtained from all study participants after a full description of the goals, potential risks and benefits, and procedures of the study. This research project adhered to the tenets of the Declaration of Helsinki and was approved by the Committee for Protection of Human Subjects, University of California, Berkeley.

2.2. Procedures

Prior to all other measurements, a CSJ image was taken by commercial spectral domain OCT (ENVISU 2300; Bioptigen Inc, Durham, NC) on each quadrant (nasal, temporal, superior, inferior) of the study eye, which was chosen by a pre-determined randomization scheme. All CSJ images were taken after a minimum 24-hour washout period before inserting contact lenses. To ensure exposure of the CSJ for imaging, subjects were instructed to look at four fixation targets, and the upper eyelid was manually lifted gently by the observer in order to image the superior CSJ. Following the collection of the CSJ images, horizontal and vertical corneal curvatures (HK and VK), radii of 0° and 90° apical curvatures, corneal shape factors, and corneal sagittal height at a chord of 10 mm at 0°, 90°, 180°, and 270° were measured by a conventional corneal topographer (E300; Medmont, Camberwell, Australia). After OCT and corneal topography measurements were completed, Acuvue Oasys lenses were provided to each subject to wear for 6 h. Ocular surface examinations were performed before and after lens wear. A Visual Analog Scale (VAS) questionnaire was administered 10 min after lens insertion and after 6 h of lens wear, providing assessments of subjective comfort on a 100-point rating scale. Contact lens fit and performance, assessed immediately after administering the first post-insertion VAS questionnaire, included lens decentration, post-blink lens movement, and push-up test tightness. A slit lamp biomicroscope with a diffuser and eyepiece reticle was used to measure post-blink lens movement. The measurements were viewed at 8x magnification and recorded to the nearest 0.1 mm. Push-up test tightness was rated on a continuous scale from 0% (very loose, falls from cornea without lid manipulation) to 100% (very tight, does not dislodge on lid manipulation). Lens decentration was calculated from measured lens conjunctival overlap (x- and y-differences between contact lens and iris observed under slit lamp) in the horizontal (temporal-nasal) and vertical (superior-inferior) meridians.

2.3. CSJ image analysis

The methodology for generating quantitative metrics describing the CSJ profile has been described in detail previously [8]. The essential steps can be summarized as follows. Using image analysis software, the surface of the CSJ is highlighted on the OCT image with an edge-finding method, then the center of the CSJ profile is marked by an experienced observer (BT). Twenty points evenly distributed along the profile spanning a 2 mm region based on the center of the CSJ profile are automatically generated. A linear regression is then performed based on the Cartesian coordinates of the 21 points, including the center of the CSJ, and the orthogonalized residuals from the regression, which are invariant to the effect of image orientation, are used to derive the SSRo metric. Large SSRo values are indicative of a steeper CSJ transitional zone and/or a more irregular CSJ surface, while smaller values represent a flatter and more even surface transition from cornea to sclera. The heterogeneity in CSJ topography is described by the SSRoV, the difference in the metric along the vertical meridian ($SSRo_{inferior}$ - $SSRo_{superior}$) and by the SSRoH, the difference along the horizontal meridian ($SSRo_{nasal}$ - $SSRo_{temporal}$). A greater deviation of the SSRoV or SSRoH from zero indicates a greater heterogeneity in CSJ topography along the vertical or horizontal meridian, respectively.

2.4. Statistical analysis

A multivariate mixed effects modeling approach was employed to analyze the relationships between comfort and potential explanatory factors and their interactions. The within- and between- subject correlations were defined as random effects. Explanatory factors such as the SSRo, measures of corneal topography, and lens fit and performance assessments were defined as fixed effects. The Wilcoxon signed-rank test, Fisher's exact test, Tukey's HSD statistic for multiple comparisons, and ordinary linear regression were used for exploratory univariate analysis in preparation for multivariate model selection and evaluation.

3. Results

3.1. Subject characteristics

Forty-four adapted SCL wearers (35 females, 9 males; 16 Asians, 16 Caucasians, 12 Latinos) ranging in age from 18 to 34 years with a mean (SD) age of 22.0 (3.6) years completed the study. Gender distribution across the three ethnic sub-groups was not significantly different ($p = 0.359$). Table 1 presents additional baseline subject information stratified on ethnicity.

3.2. Contact lens fit and performance

Table 2 reports the descriptive statistics for corneal topography and lens fit assessment. Post-blink lens movement was optimal at approximately 0.20 mm, on average [1]. Push-up test tightness was 59.4%. Lenses tended to decenter moderately toward the superotemporal quadrant, with an average decentration of 0.23 mm superiorly and 0.19 mm temporally. The mean (SD) comfort rating during lens wear was 93.5 (6.8) after lens insertion, compared with 94.2 (6.4) after 6 h of lens wear, which were not significantly different ($p = 0.569$).

3.3. CSJ topography

Fig. 1 depicts the values of the SSRo in each quadrant and stratified

Table 1
Baseline Subject Characteristics. Shown are the demographic proportions of our study sample (total n = 44 subjects), and the mean (SD) of baseline subject characteristics stratified on ethnicity.

	Asian	Caucasian	Latino
Gender			
Female	13	10	12
Male	3	6	0
Age (yrs)	22.1 (4.0)	22.4 (3.5)	21.3 (3.2)
Time awake (hrs)	2.1 (0.9)	3.4 (2.8)	1.9 (0.8)
Rx Sphere (D)	−4.56 (1.66)	−3.23 (1.94)	−2.85 (1.17)
Rx Cylinder (D)	−0.61 (0.63)	−0.36 (0.27)	−0.40 (0.33)
CL Wear Hx (yrs)	7.6 (5.2)	7.5 (2.7)	5.3 (4.2)

Table 2
Descriptive Statistics for Explanatory Variables. Shown are the mean, SD, and range for corneal topography measurements and lens fit assessments. All corneal sagittal heights were measured at a chord of 10 mm.

	Mean	SD	Range
Corneal topography			
HK (D)	43.27	1.38	[40.75, 46.75]
VK (D)	44.20	1.46	[41.62, 47.25]
PAS (mm)	10.31	1.09	[7.60, 12.20]
HVID (mm)	11.55	0.66	[8.60, 12.60]
0º Apical Curvature (mm)	7.72	0.24	[7.15, 8.14]
90º Apical Curvature (mm)	7.67	0.24	[7.16, 8.10]
Horizontal Shape Factor	0.47	0.17	[0.22, 1.24]
Vertical Shape Factor	0.19	0.10	[0.01, 0.52]
0 °Sagittal Height (μm)	1753.95	85.78	[1589.35, 1951.16]
90 °Sagittal Height (μm)	1797.90	76.14	[1651.85, 1953.57]
180 °Sagittal Height (μm)	1743.07	80.54	[1558.40, 1954.49]
270 °Sagittal Height (μm)	1806.42	79.14	[1637.53, 1989.75]
Contact Lens Fit and Performance			
Lens Power (D)	−2.00	1.98	[−6.50, −1.00]
Horizontal Decentration (mm)	0.19	0.32	[−0.40, 1.20]
Vertical Decentration (mm)	0.23	0.56	[−1.20, 1.60]
Post-blink Lens Movement (mm)	0.20	0.11	[0.00, 0.40]
Push-up test tightness (%)	59.32	8.39	[30.00, 75.00]
Post-blink Lens Movement-6hr (mm)	0.19	0.14	[0.00, 0.60]
Push-up test tightness-6hr (%)	58.30	6.90	[40.00, 75.00]

Horizontal Decentration = Conjunctival overlap (Temporal - Nasal); Vertical decentration = Conjunctival overlap (Superior - Inferior).

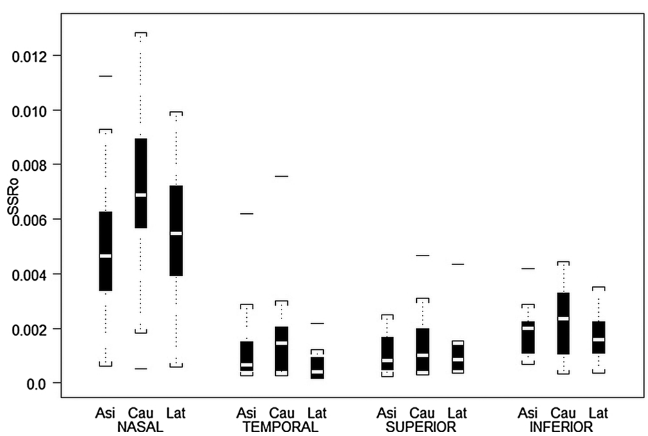

Fig. 1. The nasal quadrant has the highest values of the SSRo, on average, indicating a more pronounced angle between the corneal and scleral curves, or a more irregular surface. The inferior quadrant has lower values of the SSRo, on average, followed by yet lower values in the superior and temporal quadrants, indicating a relatively flat, even superotemporal CSJ. Caucasians show the highest values of the SSRo on average, followed by Latinos and Asians. Asi = Asian; Cau = Caucasian; Lat = Latino.

on ethnicity. Overall, the nasal quadrant had a significantly larger SSRo compared with the inferior, superior, and temporal quadrants ($p < 0.001$), suggesting a more pronounced change in radius of curvature between cornea and sclera in the nasal region, and/or a more irregular CSJ surface. No pairwise SSRo differences were shown to be statistically significant among the superior, inferior, and temporal quadrants at the family-wise $\alpha = 0.05$ level after adjustment for multiple comparisons. Asians exhibited significantly smaller SSRo in the nasal quadrant compared with Caucasians ($p = 0.014$), as well as significantly less SSRoH (Fig. 2; $p = 0.044$). No significant differences in the SSRo were detected between Caucasians and Latinos either by quadrant or overall. The SSRoH showed a significant positive relationship with horizontal lens decentration ($p = 0.006$), and a inverse relationship with horizontal corneal shape factor ($p = 0.044$). The

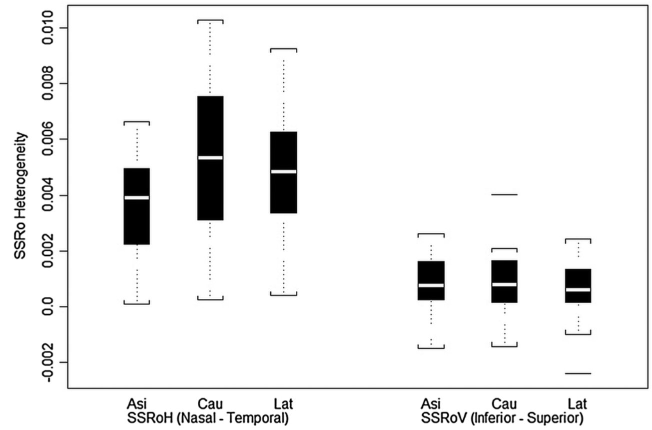

Fig. 2. Heterogeneity in the SSRo metric between quadrants was greater in the horizontal meridian compared with the vertical meridian. In the horizontal meridian, Caucasians exhibited the most heterogeneity in CSJ profile, followed by Latinos and Asians. The three ethnic groups were comparable in terms of heterogeneity in the vertical meridian. Asi = Asian; Cau = Caucasian; Lat = Latino.

Table 3a
Model of Lens-Wearing Comfort VAS Rating at 10 min Post-Lens Insertion. Shown are the significant explanatory variables, their coefficient estimates and p-values, along with the ranges of these variables observed in the sample of subjects, and the differences in comfort rating (0–100 scale) estimated by the model across each observed range, holding all other variables constant. All corneal sagittal heights were measured at a chord of 10 mm.

Variable	Coefficient	p-value	Range	Effect Size
Intercept	154.46	< 0.001	———	———
Post-blink Lens Movement (mm)	−25.13	0.011	[0.00, 0.40]	10.04
Lens Power (D)	−1.33	0.015	[−6.50, −1.00]	7.32
180 °Sagittal Height (μm)	−0.03	0.007	[1558.40, 1954.49]	11.88

Table 3b
Model of Lens-Wearing Comfort VAS Rating after 6 h **of Lens Wear.** Shown are the significant explanatory variables, their coefficient estimates and p-values, along with the ranges of the continuous variables observed in the sample of subjects, and the differences in comfort rating (0–100 scale) estimated by the model across each observed range, holding all other variables constant. For the categorical factor ethnicity, estimated comfort ratings (to which lens power and SSRoV effects are then added) are given for each group separately, along with the p-value for the factor ethnicity as a whole; the Effect Size column shows the pairwise differences between ethnic groups, with p-values adjusted for multiple comparisons.

Variable	Coefficient	p-value	Range	Effect Size
Intercept (Asian)	94.23	0.093	———	Asi-Cau: 3.40 (p = 0.092)
Caucasian	90.83		———	Asi-Lat: −1.85 (p = 0.406)
Latino	96.08		———	Cau-Lat: −5.25 (p = 0.022)
Lens Power (D)	−1.03	0.026	[−6.50, −1.00]	5.69
SSRoV (Inf–Sup)	−1839.06	0.010	[−0.0024, 0.0040]	11.77

SSRoV was positively related to corneal sagittal height for a 10 mm chord at 180° ($p = 0.024$).

3.4. Mixed effects models with comfort ratings as an outcome

Tables 3a and 3b present the best-fitting multivariable mixed effects models with contact lens-wearing comfort as a function of subject characteristics, lens fit and performance measures, and CSJ topography metrics. Contact lens-wearing comfort is quantified as VAS rating (0–100 scale) at 10 min post-lens insertion, and after 6 h of lens wear.

Table 3a shows the results for the model of lens-wearing comfort at 10 min post-lens insertion. The model indicates that lower comfort rating was significantly associated with lower contact lens power ($p = 0.015$), greater post-blink lens movement ($p = 0.011$), and greater corneal sagittal height ($p = 0.007$). According to model estimates, an increase in lens movement as great as the range observed in our subject sample was associated with an approximately 10-unit lower comfort rating on the 100-point VAS scale. The minus-power lenses of greatest dioptric power worn by our subjects (−6.50D) were associated with an approximately 7-unit higher comfort rating compared with the lowest minus-power lenses (−1.00D). The greatest corneal sagittal height (1954 μm) was associated with an almost 12-unit lower comfort rating compared with the smallest corneal sagittal height (1558 μm) we observed. CSJ topography metrics in any quadrant were not significantly related to comfort rating 10 min post-lens insertion, nor were CSJ heterogeneity in the horizontal or vertical meridians. There was no significant difference among ethnicities (Fig. 3).

Table 3b shows the results for the model of lens-wearing comfort after 6 h of lens wear. According to this model, comfort rating after 6 h of lens wear was significantly associated with contact lens power ($p = 0.026$) and heterogeneity in the SSRo metric in the vertical meridian ($p = 0.010$). Across the range of lens powers worn by our subjects, the strongest minus-power lenses (−6.50 D) were estimated to be associated with an estimated 6 units higher comfort rating, on average, compared with the weakest lens power (−1.00 D). Across the range of SSRoV (−0.0024 to +0.0040) observed among our subjects, the highest value of the CSJ heterogeneity metric was associated with an estimated 12 units lower comfort rating, compared with the least heterogeneity observed in the vertical meridian. Although the overall effect of ethnicity on comfort rating after 6 h of lens wear was not significant ($p = 0.093$), pairwise comparisons with Tukey adjustment of p-values showed an estimated 5-unit lower comfort score for Caucasians compared with Latinos ($p = 0.022$, Fig. 3). There were no significant differences between Asians and Caucasians (approximately 3 units lower comfort rating for Caucasians, $p = 0.092$) or between Asians and Latinos (approximately 2 units higher comfort rating for Latinos, $p = 0.406$).

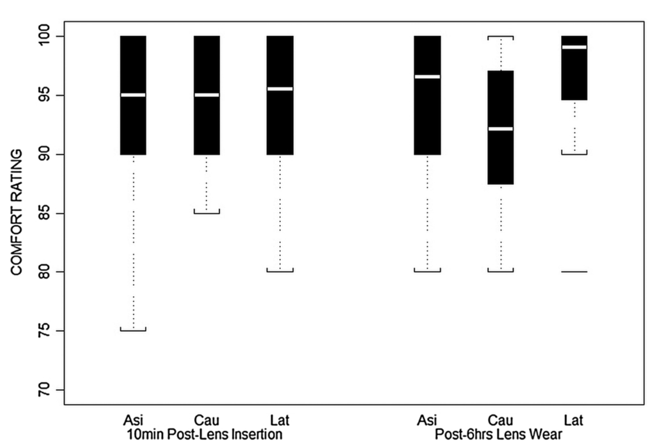

Fig. 3. VAS comfort rating 10 min post-lens insertion was generally high, and comparable among ethnic groups. After 6 h of lens wear, Latinos reported the highest comfort ratings, followed by Asians, and Caucasians with the lowest comfort ratings, on average. Asi = Asian; Cau = Caucasian; Lat = Latino.

4. Discussion

In this pilot study, we quantified the CSJ topography of a group of SCL wearers, and investigated its role as one potential contributing factor, along with lens fit and performance on the eye, to subjective comfort during Acuvue Oasys lens wear. We found that the variation of the CSJ profile among the four quadrants in our study cohort (adapted SCL wearers) was comparable to what was found in a neophyte group [11]. The CSJ has the steepest profile and/or the most irregular surface in the nasal quadrant, which is attributed to the medial rectus muscle being closest to the cornea [9], followed by the inferior quadrant, with the superior and temporal quadrants exhibiting the flattest and most even CSJ profiles. The similarity of the circum-limbal pattern of the CSJ profile between SCL wearers and neophytes also implies that SCL wear does not change the geometric properties of the CSJ or only changes them by similar magnitudes in all four quadrants. Furthermore, we found that the SSRoH showed a significant positive relationship with horizontal lens decentration, suggesting that an asymmetry of the SSRo along the horizontal meridian induces lateral lens movement temporally. A significantly inverse relationship between CSJ heterogeneity and corneal shape factor along the horizontal meridian was also found. A greater value of the corneal shape factor along any meridian indicates a flatter (i.e., with greater radius of curvature) peripheral corneal surface. As a result, the difference in radii of curvature between the peripheral cornea and the sclera is less, which suggests a more even transition from cornea to sclera and a more symmetrical CSJ between nasal and temporal quadrants. These results show that the implementation of the SSRo metric to describe the transition from cornea to sclera is superior to previous methods for analyzing the topography of the CSJ and its relationship to contact lens fit and performance.

Asians were found to have a more even corneoscleral transition in the nasal quadrant than Caucasians and Latinos. This result might be attributed to a greater corneal radius and a more prolate cornea in Asians in general [10], although we did not find this ethnic difference in ocular shape in our study cohort probably due to the particular characteristics of our subjects, who were heathy, young students and mainly females. However, we did not find a significant difference in comfort rating between Asians and other ethnicities, either at 10 min or 6 h post-lens insertion; instead, slightly but significantly lower comfort was shown in Latinos compared with Caucasians only at 6 h post-lens insertion. The lack of significantly better comfort in Asian subjects despite having a significantly more even transition from cornea to sclera suggests that evenness of the CSJ – at least in the nasal quadrant – might have minimum effect on subjective comfort. That the evenness of the CSJ in the nasal region has minimal effect on lens comfort does not necessarily imply that the contact lens edge does not impact comfort, in spite of the fact that the CSJ is the region where the lens edge of a SCL interacts with the ocular surface. It is possible, for example, that modern lens edge design and lens materials [11] permit even lens travel across the CSJ for the majority of patients, despite ethnic and inter-quadrant variability in CSJ shape.

At 10 min post-lens insertion, we found that more lens movement and greater corneal sagittal height were associated with lower comfort. It is important to note that these results were found with our particular study cohort, with their particular demographic and ocular characteristics, wearing Acuvue Oasys lenses, and care should be taken in generalizing to other types of lenses or lens-cornea fitting relationships. The relationship between corneal sagittal height and lens comfort was consistent with Hall 2011 finding [4]. We also found that comfort score after 6 h of lens wear was positively related to less SSRo heterogeneity between superior and inferior quadrants. Comfort ratings at 10 min and 6 h post-insertion were both found to be significantly related to contact lens power. However, 1D low power lenses were dispensed to 32 of 44 subjects (habitual spectacles were worn to correct residual refractive error), while 8 subjects were corrected to −6D or greater, with very few subjects in between. Thus, the association found between contact lens power and comfort in the present study might be just a cluster effect instead of a true relationship between these two factors.

As with any pilot study, there are important limitations to the present study. Comfort is a multifactorial issue, and the impact of CSJ topography as considered in the present pilot study is only one element likely to be relevant. Other factors, e.g., lid-to-lens interaction, lid tension, aperture profile and angle, corneal diameter, and relationship between lens sag and ocular sag, have been investigated and discussed broadly in many studies. In the present study, we considered the potential for CSJ topography to be an additional contributing factor in contact lens-wearing comfort as it has been relatively neglected in studies to date. In this pilot study, we quantified the CSJ topography of a group of SCL wearers, and investigated its role as one potential contributing factor, along with lens fit and performance on the eye, to subjective comfort during Acuvue Oasys lens wear. Obviously CSJ topography alone, assessed under one lens type, cannot be considered in isolation as the sole determinant of contact lens comfort; rather, we have shown in this pilot study that its impact should be considered, along with other, more extensively studied contributing factors, in any comprehensive investigation into the numerous inter-related mechanisms that ultimately combine to determine subjective comfort in contact lens wear.

There are limitations associated with the SSRo metric. First, although the SSRo corresponds directly to the difference in curvatures of the cornea and sclera, and thus the flatness or steepness of the angle between them, we have identified a few images in which the CSJ transitional region appears by visual inspection to be relatively flat, but gives an inflated SSRo value due to a very irregular or bumpy topography. Second, neither the cornea nor the sclera is a planar surface, so constructing a metric based on linear regressions of the CSJ profile along 4 discrete meridians is by nature a simplification that does not incorporate the full three-dimensional, continuous topography of the CSJ. This simplified metric, although improving over previous efforts at quantification, nevertheless could be ignoring information potentially important to contact lens behavior on the eye, and thus perhaps to lens-wearing comfort. It is possible that examining deviations across the CSJ topography and taking into account the asphericity of the anterior ocular surface could provide a better quantitative description of the effects of CSJ topography on contact lens fit and comfort. Such an approach involves significant challenges and further work will be required to determine its feasibility.

An additional limitation of this study is the fact that the study lenses were all of the same design and were fit optimally by experienced clinicians to achieve acceptable performance and subject comfort over 6 h of lens wear. In the study population at large, patients wear a wide range of lens types and brands which are fit by many different clinicians, with varying degrees of success, and a majority wear their lenses for more than 6 h at a time. It was reasonable for this pilot project to keep certain lens characteristics constant so that we could focus on basic ocular properties. In the future, our quantification method can be applied to investigate the influence of the CSJ on the lens performance and subjective comfort of various soft lens designs, in a larger, cross-sectional sample of contact lens wearers, in their variety of wearing schedules.

In conclusion, the method demonstrated in the present study quantifies the regional geometric characteristics of the CSJ without the assumptions implicit in the assigning of a simple angle between the corneal and scleral curves. We have shown that the nasal SSRo in this study cohort is significantly greater than in the other three quadrants, and that different ethnic groups may have significantly different CSJ topographies. Finally, we found that better subjective comfort after 6 h of contact lens wear was associated with a smaller difference in CSJ topography between the superior and inferior quadrants. Future investigations utilizing models of the more detailed structure of the CSJ may provide greater insight into the role of the CSJ in soft contact lens fit, on-eye performance, and comfortduring lens wear.

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Commercial relationship interest

None.

Conflict of interest

None.

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